

**Special 510(k): Device Modification**  
**INFINITY Explorer VF4****MAY 12 2004****510(k) SUMMARY**

as required per 807.92(c)

**Submitters Name, Address:**

Draeger Medical Systems, Inc.  
Danvers, MA 01923  
Tel: (978) 907-7500  
Fax: (978) 750-6879  
Official Correspondent: Connie Hertel, Director, QA/RA  
Contact person for this submission: Penelope H. Greco  
Date submission was prepared: April 5, 2004

**Trade Name, Common Name and Classification Name:****A. Trade Name:**

INFINITY Explorer

**Common Name, Classification Name, Class and Regulation Number:**

Common Name	Product Code	Class	Regulation Number
System, Network and Communication, Physiological Monitors	MSX	II	870.2300

**Legally Marketed Device Identification:**

Infinity Explorer with MDSII, 510(k) K030615  
Infinity Explorer, 510(k) K013515

**Description of Modification:**

- The INFINITY EXPLORER is a software-driven application that allows the user to extend the viewing capability of the Infinity modular monitors and integrate additional patient information on a single display. INFINITY EXPLORER is capable of displaying real-time patient data, providing control back to the bedside and integrating other applications with patient data on the PC. The VF4 modifications include:
  - New MDSII Hardware
  - New user interface with enhanced monitor applications

**Intended Use:**

The INFINITY EXPLORER is a critical care workstation intended to display physiological parameters received from INFINITY Modular Monitors and to visually display alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.

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**COMPANY CONFIDENTIAL**

**Draeger Medical Systems, Inc.**  
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43-0025

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**INFINITY Explorer VF4**

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Assessment of non-clinical performance data for equivalence: Testing in accordance with internal design control procedures indicates no new issues relative to safety and efficacy for INFINITY EXPLORER with software version VF4 and the new MDS II.

Assessment of clinical performance data for equivalence: Not applicable

Biocompatibility: Not applicable

Sterilization: Not applicable

Standards and Guidances: IEC 60601-1-1  
FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices  
FDA Guidance for Off-the-Shelf Software use in Medical Devices

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 12 2004**

Draeger Medical Systems, Inc.  
c/o Ms. Penelope Greco  
Regulatory Submissions Manager  
16 Electronics Avenue  
Danvers, MA 01923

Re: K040945

Trade Name: INFINITY Explorer with VF4 and MDS II  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac monitor (including cardiometer and rate alarm)  
Regulatory Class: II (two)  
Product Code: MSX  
Dated: April 5, 2004  
Received: April 12, 2004

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act


or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Dana R. Vachner*

 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Special 510(k) Notification**  
**INFINITY EXPLORER VF4**

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**Indications for Use**

510(k) Number (if known): K040945

Device Name: INFINITY Explorer

**Indications for Use:**

This device is capable of displaying physiological parameters received from INFINITY Modular monitors and visually displaying alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.

The device is intended to be used in an environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The device is intended for use with the adult, pediatric and neonatal populations.

**MRI Compatibility Statement:**

The INFINITY EXPLORER is not compatible for use in a MRI magnetic field.

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use       

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Dr. R. Wachner*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K040945